EXHIBIT 2

16

Study A

I. Device Description

A. Device Configurations

The metal/metal acetabular component and femoral prostheses representative of those used in the multicenter study for Study A are illustrated below.

Study A Device Configurations

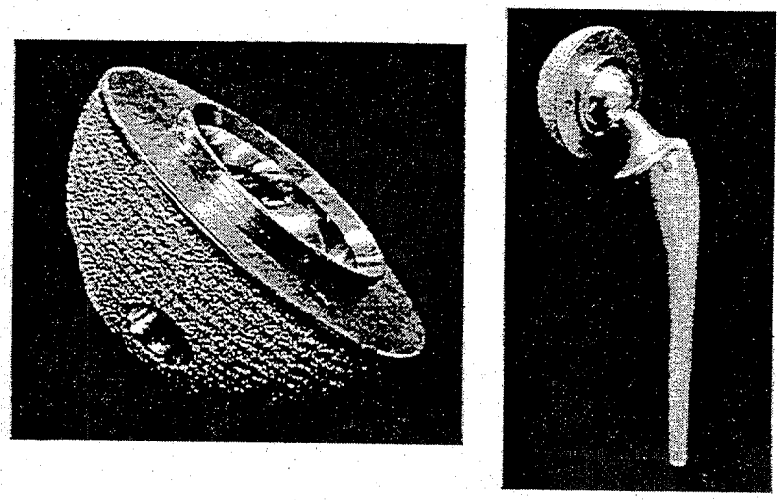

Figure 1- Device Configuration with Cemented Femoral Hip Prosthesis

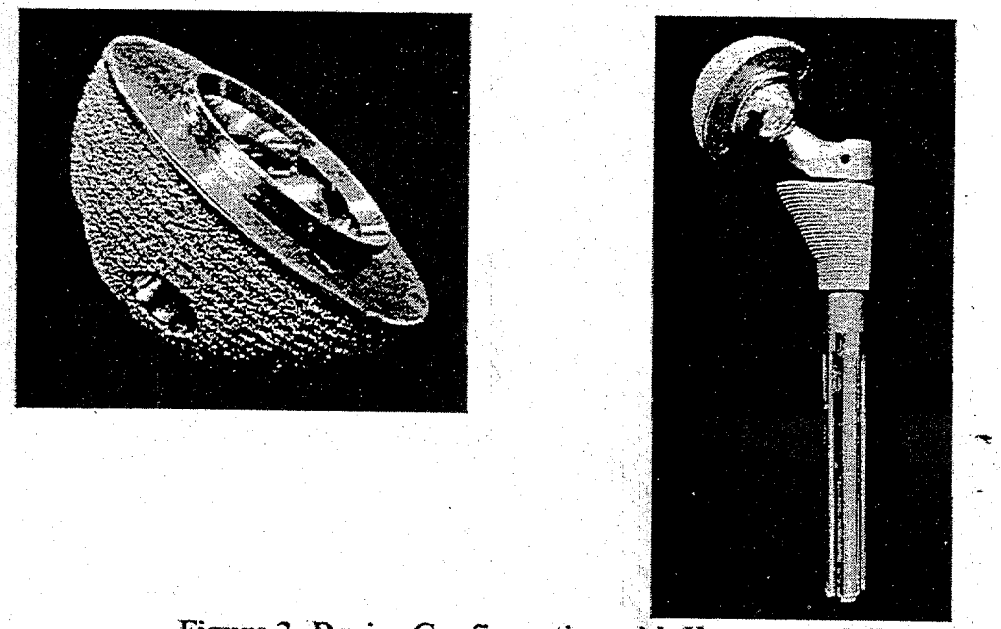

Figure 2- Device Configuration with Uncemented Femoral Hip Prosthesis

B. Device Materials

1.Femoral Prostheses-

Femoral Stem- cobalt chromium molybdenum alloy
Modular Head- cobalt chromium molybdenum alloy

2.Acetabular Prosthesis

Metal Outer Shell- titanium aluminum vanadium alloy
Metal Liner - cobalt chromium molybdenum alloy

II. Study Design

A prospective, multi-center randomized controlled clinical trial in the United States to investigate the safety and effectiveness of the metal on metal articulating acetabular system. This was a two-armed study involving cemented and uncemented femoral prostheses. For the cemented study arm, patients received the femoral prosthesis implanted with bone cement and patients in the uncemented study arm received the femoral prosthesis without cement. In each study arm patients were randomized into either the control treatment group, receiving an ultra-high molecular weight polyethylene (UHMWPE) acetabular liner, or the experimental group and received the metal acetabular liner. The liners were used in conjunction with a metal acetabular shell, femoral hip components, and cobalt-chromium modular femoral heads. The study was limited to uncemented acetabular component application only. (Refer to Figures 1,2 for illustrations of the device configurations) Patients requiring bilateral hip replacements were eligible for participation. The purpose of this metal-on-metal clinical study was to compare traditional polyethylene acetabular cup liners to metal liners in order to analyze the effectiveness, as well as the safety and durability of the metal acetabular liner device.

Non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses comprised the patient population diagnostic category. The composite diagnoses included: Osteoarthritis, avascular necrosis, developmental hip dysplasia, protrusio acetabula, crystalline arthropathy, slipped capital femoral epiphysis, and traumatic arthritis.

The Harris Hip Score was used as means of clinical assessment to determine the effectiveness of the metal liner. The primary determinants of the Harris Hip Score are pain and function. Safety was measured by the number of device-related complications, while durability was considered to be the absence of revisions. Roentgenographic data aided in the determination of osteolysis and loosening of the acetabular cup, which may increase the potential for revisions.

III. Patient Population

The control and experimental groups were equally matched in terms of demographics (Refer to Patient Demographics table for age, gender and diagnosis demographics)

PATIENT DEMOGRAPHICS
STUDY A

	METAL/METAL		METAL/POLYETHYLENE	
	N	MEAN	N	MEAN
AGE	219	55.7	206	57.0
GENDER	FEMALES 104 (47.5%)	MALES 115 (52.5%)	FEMALES 79 (38.3%)	MALES 127 (61.7%)
NIDJD DIAGNOSIS	N	PERCENT	N	PERCENT
OSTEOARTHRITIS	164	74.9	152	73.8
AVASCULAR NECROSIS	29	13.2	33	16.0
POSTTRAUMATIC	11	5.0	10	4.9
CONGENITAL HIP DYSPLASIA	8	3.7	8	3.9
OTHER	7	3.2	3	1.5
TOTAL	219	100.0	206	100.0

IV. Results

Tables 1-6 of the section tabbed as Study A of Appendix 1 provide summaries of the overall results for Study A. Tables 1-37 of Appendix 2 provide tabulations of the individual clinical and radiographic parameters and the demographics for studies A, B, and C.

Study B

I. Device Description

A. Device Configurations

The metal/metal acetabular component and femoral prostheses representative of those used in the multicenter study for Study B are illustrated below.

Study B Hip Prostheses Device Configurations

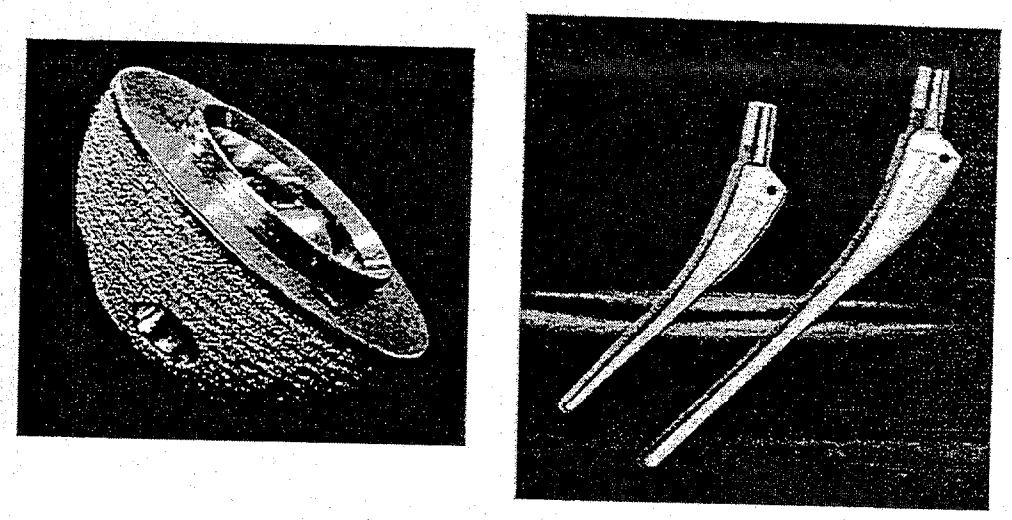

Figure 3- Device Configuration with Cemented Femoral Hip Prosthesis

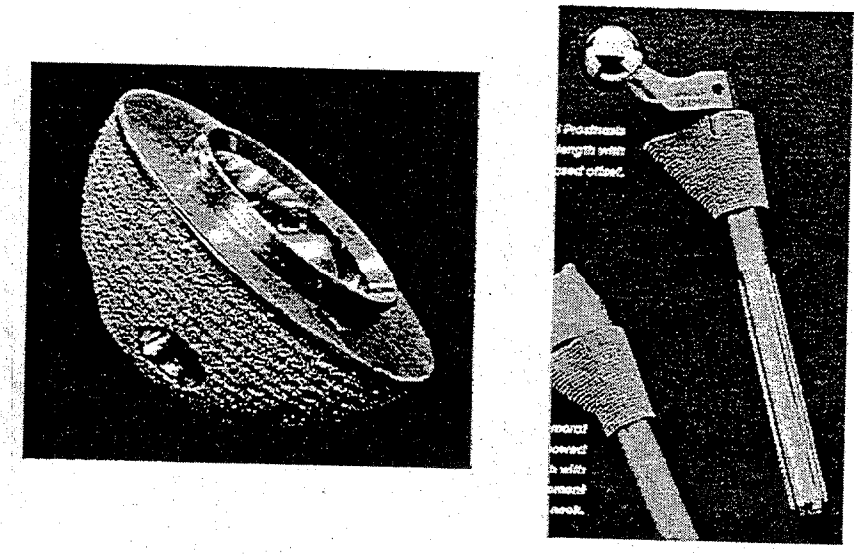

Figure 4- Device Configuration with Uncemented Femoral Hip Prosthesis

B. Device Materials:

1.Femoral Prostheses

Femoral Stem- cobalt chromium molybdenum alloy; titanium aluminum vanadium alloy

Modular Head- cobalt chromium molybdenum alloy

2.Acetabular Prosthesis

Metal Outer Shell- titanium aluminum vanadium alloy
Metal Liner - cobalt chromium molybdenum alloy

II. Study Design

A prospective, multi-center, open clinical trial in Europe to primarily investigate the safety of an acetabular component with a metal bearing surface. All patients were enrolled into the experimental group and received the metal acetabular liner. The liners were used in conjunction with a metal acetabular shell, femoral hip components, and cobalt-chromium modular femoral heads. In addition, the study was limited to uncemented acetabular component application only. Five different styles of cemented and uncemented femoral prostheses were included. (Refer to Figures 3,4 for illustrations of the device configurations) Patients requiring bilateral hip replacements were not eligible for participation. The primary purpose of this metal-on-metal clinical study was to obtain short-term, i.e., less than 12 months, data on complications in order to analyze the safety of the metal acetabular liner device. Comparison of the tabulated study results were made to literature based (historical) controls.

Non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses comprised the patient population diagnostic category. The composite diagnoses included: Avascular necrosis, congenital dysplasia of the hip, Legg-Calve-Perthes disease, osteoarthritis, and traumatic arthritis.

The Harris Hip Score was used as means of clinical assessment to determine the short-term effectiveness of the metal liner. The primary determinants of the Harris Hip Score are pain and function. Safety was measured by the number of device-related complications, while durability was considered to be the absence of revisions. Roentgenographic data aided in the determination of osteolysis and loosening of the acetabular cup, which may increase the potential for revisions.

III. Patient Population

The control and experimental groups were equally matched in terms of demographics (Refer to Patient Demographics table for age, gender and diagnoses demographics)

PATIENT DEMOGRAPHICS
STUDY B

	METAL/METAL	
	N	MEAN
AGE	87	57.4
	FEMALES	MALES
GENDER	35 (40.2%)	52 (59.8%)

NIDJD DIAGNOSIS	N	PERCENT
OSTEOARTHRITIS	74	85.1
POSTTRAUMATIC	1	1.1
CONGENITAL HIP DYSPLASIA	6	6.9
OTHER	6	6.9
TOTAL	87	100.0

IV. Results

Tables 1-6 of the section tabbed as Study B of Appendix 1 provide summaries of the overall results for Study B. Tables 1-37 of Appendix 2 provide tabulations of the individual clinical and radiographic parameters and the demographics for studies A, B, and C.

Study C

I. Device Description

A. Device Configurations

The metal/metal acetabular component and femoral prostheses representative of those used in the multicenter study for Study C are illustrated below.

Study C Hip Prostheses Device Configurations

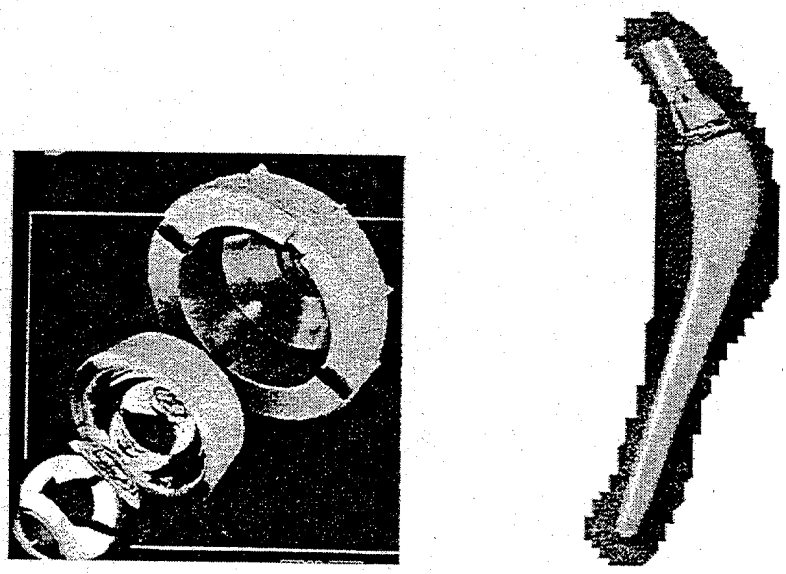

Figure 5- Device Configuration with Cemented Femoral Hip Prosthesis

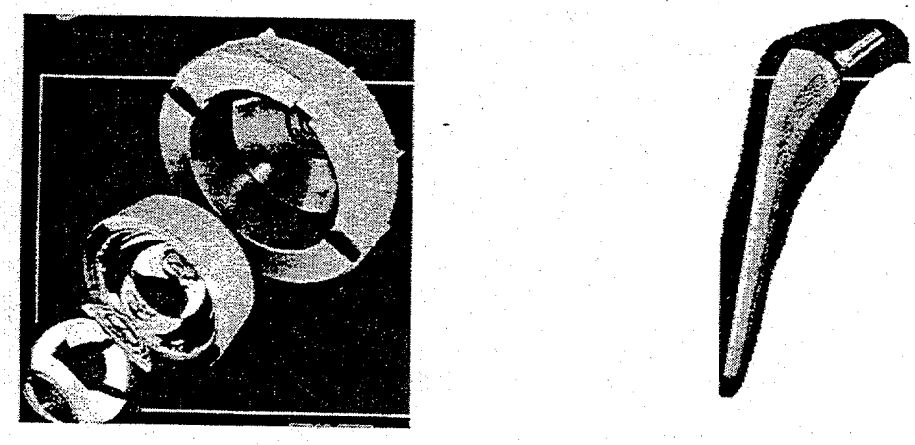

Figure 6- Device Configuration with Uncemented Femoral Hip Prosthesis

B. Device Materials:

1.Femoral Prostheses

Femoral Stem- cobalt chromium molybdenum alloy; titanium aluminum vanadium alloy

Modular Head- cobalt chromium molybdenum alloy

2.Acetabular Prosthesis

Metal Outer Shell- titanium aluminum vanadium alloy

Metal Liner - cobalt chromium molybdenum alloy

II. Study Design

A prospective, multi-center randomized controlled clinical trial in the United States to investigate the safety and effectiveness of the metal on metal articulating acetabular system. Patients were randomized into either the control treatment group, receiving an ultra-high molecular weight polyethylene (UHMWPE) acetabular liner, or the experimental group and received the metal acetabular liner. The liners were used in conjunction with a metal acetabular shell, femoral hip components, and cobalt-chromium modular femoral heads. In addition, the study was limited to uncemented acetabular component application only. Seven different styles of femoral prostheses were included. (Refer to Figures 5,6 for illustrations of the device configurations) Patients requiring bilateral hip replacements were eligible for participation. The purpose of this metal-on-metal clinical study was to compare traditional polyethylene acetabular cup liners to metal liners in order to analyze the effectiveness, as well as the safety and durability of the metal acetabular liner device.

Non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses comprised the patient population diagnostic category. The composite diagnoses included: Avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, Legg-Calve-Perthes disease, osteoarthritis, slipped capital femoral epiphysis, and traumatic arthritis.

The Harris Hip Score was used as means of clinical assessment to determine the effectiveness of the metal liner. The primary determinants of the Harris Hip Score are pain and function. Safety was measured by the number of device-related complications, while durability was considered to be the absence of revisions. Roentgenographic data aided in the determination of osteolysis and loosening of the acetabular cup, which may increase the potential for revisions.

III. Patient Population

The control and experimental groups were equally matched in terms of demographics (Refer to Patient Demographics table for age, gender and diagnosis demographics)

PATIENT DEMOGRAPHICS
STUDY C

	METAL/METAL		METAL/POLYETHYLENE	
	N	MEAN	N	MEAN
AGE	97	49.8	97	50.3
GENDER	FEMALES 26 (26.8%)	MALES 71 (73.2%)	FEMALES 25 (25.8%)	MALES 72 (74.2%)
NIDJD DIAGNOSIS	N	PERCENT	N	PERCENT
OSTEOARTHRITIS	75	77.3	72	74.2
AVASCULAR NECROSIS	12	12.4	14	14.4
POSTTRAUMATIC	6	6.2	7	7.2
OTHER	4	4.1	4	4.1
TOTAL	97	100.0	97	100.0

IV. Results

Tables 1-6 of the section tabbed as Study C of Appendix 1 provide summaries of the overall results for Study C. Tables 1-37 of Appendix 2 provide tabulations of the individual clinical and radiographic parameters and the demographics for studies A, B, and C.

Study D

I. Device Description

A. Device Configurations

The metal/metal acetabular component and femoral prostheses representative of those used in the multicenter study for Study D are illustrated below.

Study D Hip Prostheses Device Configurations

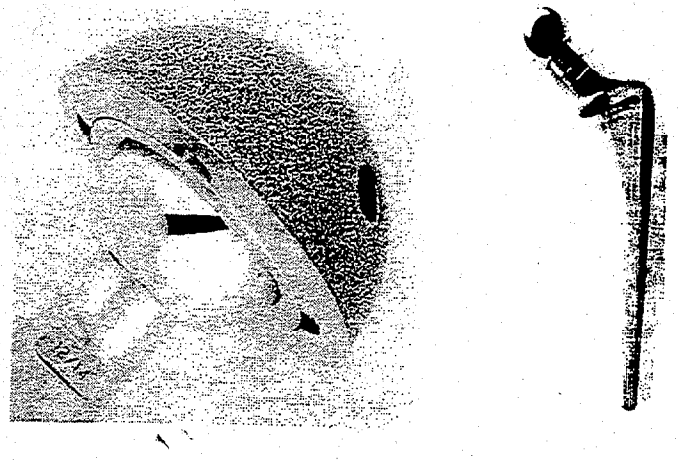

Figure 7- Device Configuration with Cemented Femoral Hip Prosthesis

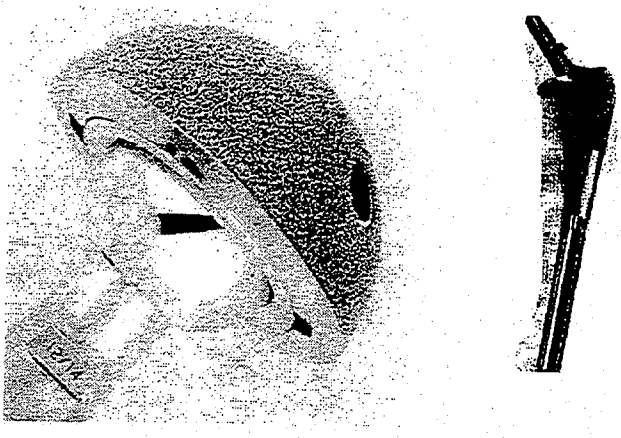

Figure 8- Device Configuration with Uncemented Femoral Hip Prosthesis

B. Device Materials

1.Femoral Prostheses

Femoral Stem- cobalt chromium molybdenum alloy; titanium aluminum vanadium alloy

Modular Head- cobalt chromium molybdenum alloy

2.Acetabular Prosthesis

Metal Outer Shell- titanium aluminum vanadium alloy

Metal Liner - cobalt chromium molybdenum alloy

II. Study Design

A prospective, multi-center, historical clinical trial in the United States to investigate the safety and efficacy of an acetabular component with a metal bearing surface. All patients were enrolled into the experimental group and received the metal acetabular liner. The liners were used in conjunction with a metal acetabular shell, femoral hip components, and cobalt-chromium modular femoral heads. In addition, the study was limited to uncemented acetabular component application only. Eight different styles of cemented and uncemented femoral prostheses were included. (Refer to Figures 7,8 for illustrations of the device configurations) Patients requiring bilateral hip replacements were not eligible for participation. The purpose of this metal-on-metal clinical study was to compare literature results of traditional polyethylene acetabular cup liners to study results of metal liners in order to analyze the effectiveness, as well as the safety and durability of the metal acetabular liner device.

Non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses comprised the patient population diagnostic category. The composite diagnoses included: Avascular necrosis, congenital dysplasia of the hip, osteoarthritis, and traumatic arthritis.

The Harris Hip Score was used as means of clinical assessment to determine the short-term effectiveness of the metal liner. The primary determinants of the Harris Hip Score are pain and function. Safety was measured by the number of device-related complications, while durability was considered to be the absence of revisions.

III. Patient Population

The control and experimental groups were equally matched in terms of demographics (Refer to Patient Demographics table for age, gender and diagnoses demographics)

TABLE 1
PATIENT DEMOGRAPHICS
STUDY D

	METAL/METAL	
	N	MEAN
AGE	221	54
	FEMALES	MALES
GENDER	88 (40%)	133 (60%)

NIDJD DIAGNOSIS	N	PERCENT
OSTEOARTHRITIS	174	78.7
AVASCULAR NECROSIS	34	15.4
POSTTRAUMATIC	7	3.2
CONGENITAL HIP DYSPLASIA	4	1.8
OTHER	2	0.9
TOTAL	221	100.0

IV. Results

Tables 1-6 of the section tabbed as Study A of Appendix 1 provide summaries of the overall results for Study D.